

Applicants' claims 1-3 and 5-9 under Section 102(e) and that Kim also fails as a reference supporting the assertion of obviousness of claims 4 and 10-13 (which claims ultimately depend from claim 1) under Section 103.

It is not believed that any fees are due. However, should any fee be required, please charge the same to Deposit Account No. 02-4467. A duplicate copy of this paper is enclosed.

REMARKS

§102(e) Rejection

Claims 1-3 and 5-9 were rejected under 35 U.S.C. §102(e) as being unpatentable over Kim *et al*, U.S. Patent No. 5,648,225 ("Kim"). (Paper no. 22, para. 5). For the reasons described in the interview and presented below, however, reconsideration and withdrawal of the rejection respectfully is solicited.

Kim discloses a multipurpose reagent for rapid analysis of a whole blood sample. (Abstract). In one embodiment disclosed by Kim, "a nuclear stain, e.g., ethidium homodimer, is added to the multipurpose reagent system before it is added to [a] blood sample." (Column 8, lines 35-38). Another embodiment discloses "mixing flouochrome-conjugated monoclonal antibodies... with whole blood samples before adding the multipurpose reagent system." (Column 9, lines 1-5).

As such, Kim discloses two separate embodiments, one where a stain is mixed, and one where monoclonal antibodies are added first to a blood sample. Based on this, the Examiner contends that all of the Applicants' claim limitations "are disclosed for the same use or

purpose in flow cytometry.” (Final Office Action, para. 4(a), p. 4) Even accepting this proposition, arguendo, (although Applicants respectfully disagree with it) this nonetheless fails to render Applicants’ claims anticipated because nowhere does Kim disclose adding or using *both* monoclonal antibodies and nuclear stains in the same process.

This lack of disclosure is fatal to the rejection because, as Applicants have stated previously, anticipation under §102 requires “identity of invention.” *Glaverbel Societ Anonyme v Northlake Mktg. & Supply.*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). An ad hoc selection of elements from separate and distinct disclosed embodiments is insufficient to meet this burden because anticipation demands that each and every element recited in a claim must be found in a single prior art reference and *arranged as in the claim*. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindeman Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984).

In this case such arrangement of claimed elements pertains to a single process. Because Kim does not describe or suggest using both a nuclear stain and monoclonal antibodies in the same process, Kim does not disclose the elements of claim 1 as arranged with respect to the process recited in the claim. Selectively combining embodiments disclosed is not “identity of invention” and does not demonstrate anticipation. As such, reconsideration and withdrawal of the rejection is respectfully solicited.

§103(a) Rejection

Claims 4 and 10-13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kim and Inami et al., U.S. Patent No. 5,298,426 (“Inami”). (Paper no. 22, para. 6). For the

reasons described in the interview and presented below, however, reconsideration and withdrawal of the rejection respectfully is solicited.

Applicants previously argued that the combination of references fail to disclose the affirmative manipulative steps taken with respect obtaining, analyzing and discriminating based on two signal types, i.e. a nucleotide fluorescent signal and a fluorescent labeled antibody signal, as recited in Applicants' claims. While the Examiner contends that these gaps are filled by the combination of Kim and Inami, neither of these citations discloses acting upon these two signals together according to Applicants' method claims. Moreover, as described previously, Kim fails to disclose a method or embodiment that employs both a nucleic stain and monoclonal antibodies. Inami, disclosing use only of a nucleic stain with a two-reagent buffering system, and not disclosing use of fluorescent binding antibodies, does not address this fundamental gap presented by Kim.

Therefore, at the very least, the Applicants' claimed steps of detecting, analyzing, and discriminating *between these two signals*, are necessarily absent and the Examiner's rejection improperly fails to account for them.

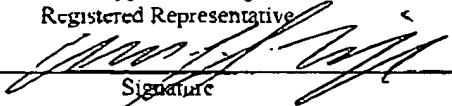
To reject claims to a method, the references relied upon by the Examiner must account for the manipulative steps claimed. *In re Magat*, 112 USPQ 317, 319 (CCPA 1957). Here, the manipulative steps of Applicants' method as claimed act on two separate signals, and neither Kim nor Inami discloses a method to analyze both of these two signals and discriminate cells based thereon. Moreover, there is no support for the Examiner's proposition that one of skill in the art would substitute the buffer in the reagent of Kim with the two reagent system of Inami. Modifying the disclosures of Kim and Inami to meet Applicants' claims, must, by

necessity, involve speculation beyond the disclosure of the two references. And no facts or evidence adduced supports such modification.

As such, the Examiner's rejection falls far short of providing the requisite motivation to deviate from Kim to arrive at the claimed invention. The citations must "suggest the desirability of the combination" that is claimed. See MPEP 2143.01 at 2100-110, 111 and MPEP 2145 (j) 3 at 2100-127. This MPEP section further requires that "Obviousness can only be established by combining or modifying the teaching of the prior art to produce the claimed invention where there is *some teaching, suggestion or motivation* to do so..." (Emphasis added). No teaching, suggestion or motivation in Kim or Inami supports any modification of the disclosures therein to arrive at what the Applicants have claimed.

In sum, the Examiner has not adduced factual support demonstrating the requisite motivation for the combination of references advanced against Applicants' claims. In addition, the citations fail to account for all the Applicants' claim limitations and lack any disclosure motivating their combination. The Examiner has not met her burden of demonstrating a *prima facie* case of obviousness, therefore, the rejection should be withdrawn.

In view of the foregoing, favorable action on the merits, and allowance of all claims, respectfully is solicited.

I hereby certify that this correspondence is being transmitted via facsimile at (703) 305-3014, and addressed to the Commissioner for Patents, Washington, D.C. 20231, on October 30, 2002.
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